

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government: The bill creates an additional responsibility for the DOH and authorizes the development of additional rules.

Ensure lower taxes. The bill permits a participant facility dispensing cancer drugs or supplies under the proposed donation program, to charge a handling fee “sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies....”

Promote personal responsibility: The bill allows individuals to contribute cancer drugs on a voluntary basis.

Empower families: The bill provides opportunities for certain families with limited resources to pursue less costly cancer treatments.

B. EFFECT OF PROPOSED CHANGES:

EFFECT OF HB 371 CS

HB 371 CS creates the Cancer Drug Donation Program Act under s. 381.94, F.S. The bill requires the DOH to establish and maintain a cancer drug and supplies donation program under which a donor defined as a patient or patient representative, physician, health care facility, nursing home, hospice, or hospital pharmacy may donate cancer drugs provided that it has been maintained within a closed drug delivery system¹ or supplies needed to administer cancer drugs for use by an individual who meets eligibility criteria specified by the DOH in rule. Drug manufacturers, medical device manufacturers or suppliers, wholesalers of drugs or supplies may also donate cancer drugs or supplies to the program. The DOH is authorized to adopt rules for the implementation of the program.

Donations may be made only at a hospital pharmacy that elects or volunteers to participate in the program. A dispensing pharmacy may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. Under the bill, a cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container or packaging. A cancer drug cannot be accepted or dispensed under the program if it bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled.

A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, or by any other prescription drug program funded in whole or in part by the federal government, or by any other prescription drug program offered by a third-party insurer, is ineligible to participate in the program, unless benefits have been exhausted, or a certain cancer drug or cancer supply is not covered by their prescription drug program.

The bill requires the DOH to establish and maintain a participant facility (i.e., hospital pharmacy) registry for the program. The registry must include the name, address, and telephone number of the facility. The DOH must make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The DOH web site shall also contain links to cancer drug manufacturers that offer drug assistance programs or offer free medication.

Under the act, a donor of cancer drugs or supplies or a program participant who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program is

¹ Defined in the bill as a system in which the actual control of the unit-dose medication package is maintained by a facility rather than by the individual patient.

immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to activities of the program.

In addition, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under the program, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug as well as the expiration date of the transferred drug.

Because the bill creates new law and allows the donation of cancer drugs or supplies currently prohibited by statute and regulations, the bill provides that if any conflict exists between the provisions contained in the newly created s. 381.94, F.S., and provisions in Chapter 465, F.S.,² or Chapter 499, F.S.,³ the provisions contained in s. 381.94, F.S., shall control as to the operation of the Cancer Drug Donation Program Act.

The bill includes a specific appropriation of \$65,508 from the General Revenue Fund for FY 2006-07 to fund DOH costs to administer the program.

BACKGROUND AND CURRENT SITUATION

Cancer is a general term for a group of diseases in which abnormal cells grow out of control. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body.⁴ Cancer is the second leading cause of death in Florida and in the United States. In 2005, an estimated 570,000 Americans—or more than 1,500 people a day—were expected to die of cancer. Of these annual cancer deaths, 40,090 are expected in Florida. In addition, approximately 1.4 million new cases of cancer were expected to be diagnosed nationally. This figure includes an estimated 96,200 new cases that were likely to be diagnosed in Florida.⁵

Estimated New Cases of Cancer – 2005		
Types of Cancers	US	FL
All Cancers	1,372,910	96,200
Breast (female)	211,240	13,430
Uterine Cervix	10,370	730
Colon & Rectum	145,250	9,860
Uterine Corpus	40,880	2,520
Leukemia	34,810	2,620
Lung & Bronchus	172,570	13,130
Melanoma of the skin	59,580	4,600
Non-Hodgkin Lymphoma	56,390	3,470
Prostate	232,090	19,650
Urinary Bladder	63,210	4,890

The financial costs of cancer treatment are a burden to people diagnosed with cancer, their families, and society as a whole. Nationally, cancer treatment accounted for an estimated \$72.1 billion in 2004 in spending.⁶ The cost of treating cancer varies greatly by the type of cancer an individual has been diagnosed to have.

² Regulation of pharmacies.

³ Regulation of drug, cosmetic, and household products.

⁴ National Cancer Institute – Dictionary of Cancer Terms.

⁵ Source: Cancer Facts & Figure, American Cancer Society, 2005.

⁶ 1963-1995: Brown ML, Lipscomb J, Snyder C. The burden of illness of cancer: economic cost and quality of life. Annual Review of Public Health 2001;22:91-113. : NIH Report to the U.S. Congress, 2005; National Health Care Expenditures Projections: 2003-2013

	Percent of all new cancers (1998)	Expenditures (billions; in 2004 dollars)	Percent of all cancer treatment expenditures	Average Medicare first year cost (2004 dollars)
Lung	12.7%	\$9.6	13.3%	\$24,700
Breast	15.9%	\$8.1	11.2%	\$11,000
Colorectal	10.7%	\$8.4	11.7%	\$24,200
Prostate	16.8%	\$8.0	11.1%	\$11,000
Lymphoma	4.6%	\$4.6	6.3%	\$21,500
Head/Neck	2.8%	\$3.2	4.4%	\$18,000
Bladder	4.4%	\$2.9	4.0%	\$12,300
Leukemia	2.4%	\$2.6	3.7%	\$18,000
Ovary	1.9%	\$2.2	3.1%	\$36,800
Kidney	2.6%	\$1.9	2.7%	\$25,300
Endometrial	2.9%	\$1.8	2.5%	\$16,200
Cervix	0.8%	\$1.7	2.4%	\$20,100
Pancreas	2.3%	\$1.5	2.1%	\$26,600
Melanoma	4.0%	\$1.5	2.0%	\$4,800
Esophagus	1.0%	\$0.8	1.1%	\$30,500
All Other	14.0%	\$13.4	18.5%	\$20,400

Lack of health insurance and other barriers to health care prevent many Americans from receiving optimal medical care. According to the 2003 national health survey data, there are approximately 2.9 million Floridians who lack health insurance.

Insurance Status of Floridians

Source of Insurance	FL Population	%	US Population	%
Employer	7,956,640	48	156,270,570	54
Individual	990,350	6	13,593,990	5
Medicaid	2,007,000	12	38,352,430	13
Medicare	2,726,250	16	34,190,710	12
Uninsured	2,957,290	18	44,960,710	16
Total	16,637,520	100	287,368,410	100

(Source: Kaiser Foundation - Population Distribution by Insurance Status, state data 2002-03, U.S. 2003)

According to National Institute of Health (NIH) - Cancer Institute, there are 500 agents (i.e., drugs) that are being used in the treatment of patients with cancer or cancer-related conditions.⁸ There are estimates that consumers leave unused approximately \$1 billion worth of unused prescription drugs⁹ per year.

Cancer drug donation or repository program

To address the issue of affordability of treatment and unused prescription medication to treat cancer, some states have established a cancer drug donation or repository program to accept unused, unopened, prescription drugs and medical supplies. Wisconsin,¹⁰ Colorado,¹¹ and Nebraska,¹² are among the states that have passed cancer drug donation laws. Several other states are considering similar legislation.¹³

⁷ Cancer Trend Progress Report – 2005 Update, U.S. National Institute of Health – National Cancer Institute.

⁸ NCI Drug Dictionary, NIH-National Institute of Health, 2005.

⁹ "Old Pills Finding New Medicine Cabinets," NY Times, May 18, 2005. This reference is to all prescription drugs not just drugs to treat cancer.

¹⁰ Section 255.056, Wisconsin Statutes.

¹¹ Section 25-35-101, Colorado Statute.

¹² Title 181 Chapter 6, Nebraska Statute.

¹³ National Conference of State Legislatures, 2005 Summary of Prescription Drug State Legislation.

In general, the cancer donation programs being established in other states have similar characteristics. These characteristics include, but are not limited to:

- A mechanism to accept unused, unopened, individually packaged prescription drugs and medical supplies from individuals and health care facilities and these would be redistributed to uninsured and under-insured cancer patients.
- Preference being given to the uninsured for access to donated drugs and supplies.
- Donated drugs being distributed only when prescribed by a doctor and dispensed by a pharmacist.
- Donated drugs and supplies being in their original, unopened, sealed and tamper-evident packaging.
- Health facilities being able to charge a handling fee for dispensing donated cancer drugs but may not resell donated drugs.
- Having a central registry operated by a state agency to track participating facilities.

Relevant Statutory Provisions

Section 465.016, F.S.

Section 465.016(1) (l), F.S., prohibits a pharmacy from placing into stock any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which dispensed unit dose medication is transferred to the facility for administration, these may be returned.

Chapter 499, F.S.

The Florida Drug and Cosmetic Act is codified in ch. 499, F.S. The Act defines “wholesale distribution” to mean distribution of prescription drugs to persons other than a consumer or patient, but does not include specified activities. Chapter 499, F.S., provides safeguards for the public health and protection from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The chapter provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

Section 499.014, F.S., authorizes the distribution of prescription drugs by a charitable organization under a limited permit issued by the DOH.

Section 893.13, F.S.

Section 893.13, F.S., provides that, except as authorized by Chapter 893, F.S., (i.e., Drug Abuse Prevention and Control) and Chapter 499, F.S., it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance.

Florida Administrative Code

The DOH has adopted rules governing the issuance of a restricted prescription drug distribution permit for charitable organizations, and for the operation of their organizations under this permit.¹⁴

Relevant Government Agencies

U.S. Food and Drug Administration (FDA)

The FDA is the federal agency responsible for ensuring that foods, drugs, biological products, and medical devices are safe and effective. Under section 505 of Federal Food, Drug, and Cosmetic Act, no drug can be introduced or delivered for introduction into interstate commerce unless approved by the FDA.

¹⁴ Rules 64F-12.015(8)(c) and 64F-12.023(1), F.A.C.

The FDA has no specific regulations regarding cancer drug donation programs and leaves the cancer donation program to the discretion of the state as long as the state enforces applicable regulations relating to prescription medication.¹⁵

Department of Health

The Bureau of Statewide Pharmaceutical Services is responsible for enforcing Florida's Drug and Cosmetic Act, Chapter 499, F.S. The purpose of this act is to safeguard the health of the public and protect the public from injury by product use and merchandising deceit involving drugs, devices and cosmetics, as well as false and misleading advertising. The Bureau also provides pharmaceuticals to County Health Departments annually and administers the State of Florida's pharmaceutical contracts.

Agency for Health Care Administration

Hospitals are subject to oversight by the Agency for Health Care Administration and most are accredited by the Joint Commission for Healthcare Organizations. These entities have policies for reviewing pharmacy operations in hospitals.

C. SECTION DIRECTORY:

Section 1: Creates s. 381.94, F.S., to establish the Cancer Drug Donation Program under the DOH.

Section 2. Establishes an effective date for the act of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

According to the DOH, 1 full-time equivalent position is needed to create and maintain the registry, to provide consultation and technical assistance, and to perform other administrative functions.

	<u>FY 06-07</u>	<u>FY 07-08</u>
Salary and Expenses	(\$65,308)	(\$71, 079)

The bill includes a specific appropriation of \$65,508 from the General Revenue Fund for FY 2006-07 to fund DOH costs to administer the program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

¹⁵ Telephone discussion with FDA concerning HB 371, Stewart Watson, REHS LCDR, USPHS, Public Affairs Specialist Florida District – FDA.

For a hospital pharmacy that elects or volunteers to participate in the program, there will be costs associated with the processing, storage, dispensing and disposal of donated cancer drugs and supplies. These costs could be recovered fully or in part by the handling fee authorized in the bill to cover the cost of preparing and dispensing the cancer drugs or supplies under the program. The fee will be established in rules adopted by the DOH.

D. FISCAL COMMENTS:

According to the DOH, in order to dispense donated drugs to eligible recipients, participating hospital pharmacies will be required to obtain a Community Pharmacy Permit thus incurring an additional cost of \$255.00 for licensure.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take any action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The act authorizes the DOH to adopt implementing rules to include:

- Eligibility criteria, including a method to determine priority of eligible patients under the program.
- Standards and procedures for participants that accept, store, distribute, or dispense donated cancer drugs or supplies.
- Necessary forms for administration of the program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.
- The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.
- Categories of cancer drugs and supplies that the program will accept for dispensing.
- Categories of cancer drugs and supplies that the program will not accept for dispensing and the reason that such drugs and supplies will not be accepted.
- Maintenance and distribution of the participant registry.

However, the bill does not provide the DOH with any guidance as part of this delegated authority: The bill gives the agency broad discretion on formulating rules.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 15, 2006, the Judiciary Committee adopted two amendments and reported the bill favorably as a CS. The CS differs from the CS as reported by the Health Care Committee in that the Judiciary Committee CS:

- 1) reverts back to the liability provisions found in the original bill as filed. The amendment immunizes donors of cancer drugs or supplies and program participants from civil and

criminal liability and professional disciplinary action when they exercise reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies.

- 2) limits non-liability to pharmaceutical manufacturers and only for injuries resulting from the transfer of any cancer drug under this program. The CS removes manufacturers of cancer supplies from this provision.
- 3) provides a specific appropriation of \$65,308 from the General Revenue Fund to fund the Department of Health's costs to administer the program.

Previously, on January 11, 2006, the Health Care General Committee adopted one amendment to the bill. The amendment:

- Restricts cancer drugs to those approved by the FDA.
- Defines closed drug delivery system.
- Changes the definition of "donor" to include only cancer drugs that have been maintained within a closed drug delivery system.
- Defines "nursing home."
- Changes the definition of "Participant facility" to mean a class II institutional hospital pharmacy.
- Strengthens provisions to ensure the integrity of a donated drug.
- Provides that a donation of cancer drugs can be made only at a participant facility.
- Allows the DOH to exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.
- Excludes a person receiving Medicaid or any other prescription drug program funded in whole or in part by the federal government (e.g., Medicare), or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or cancer supply is not covered by the prescription drug program.
- Requires the DOH to maintain a cancer drug donation program web site and links to cancer supply manufacturers that offer drug assistance programs or offer free medication.
- Adds cancer supply manufacturers to those immune from liability for any claim or injury arising from the donation and use of any donated cancer drug.
- Provides that if any conflict exists between the provisions contained in s. 381.94, F.S., and provisions in Chapter 465, F.S., or Chapter 499, F.S., the provisions contained in s. 381.94, F.S., shall control as to the operation of the Cancer Drug Donation Program.

As amended, the bill was reported favorably as a committee substitute.